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Attorney Docket No. PP16073.021 (2300-16073.10)

PATENT

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By: 

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Chien et al.

Serial No.: 10/643,853

Examiner: Not Assigned

Confirmation No.: 6313

Art Unit: 1632

Filed: August 19, 2003

For: HCV ANTIGEN/ANTIBODY COMBINATION ASSAY

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Enclosed is an Information Disclosure Statement and accompanying Form PTO/SB/08A for the above-identified patent application.

- ☒ In accordance with 37 C.F.R. §1.97(b), no additional fee for submission of the IDS is required.
- ☐ In accordance with 37 C.F.R. §1.97(c), also enclosed is:
- ☐ the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p); or
  - ☐ a statement as specified in 37 C.F.R. §1.97(e).
- ☐ In accordance with 37 C.F.R. §1.97(d), a statement as specified in 37 C.F.R. § 1.97(e) and the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) are also enclosed.
- ☐ Check No. \_\_\_ in the amount of \$\_\_\_ for the total fee is attached.

☒ [X] A return receipt postcard is also enclosed.

☐ [] Please charge \$\_\_\_\_\_ to Deposit Account No. 18-1648 for the total fee.  
This paper is being submitted in duplicate.

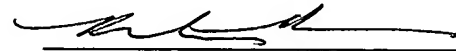
The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 18-1648.

Dated: 12/13/04

Respectfully submitted,

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Attorney Docket No. PP16073.021 (2300-16073.10)

PATENT

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By: [Signature]

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of CHIEN et al.

Serial No.: 10/643,853

Examiner: Unassigned

Confirmation No.: 6313

Art Unit: 1632

Filed: August 19, 2003

For: HCV ANTIGEN/ANTIBODY COMBINATION ASSAY

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.97(b)**

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant(s) hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98.

- ☒ Pursuant to 37 C.F.R. §1.98, a copy of each document cited in the attached Form PTO-1449 is enclosed.
- ☐ No copies of the publications listed on the attached Form PTO-1449 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No. \_\_\_\_\_ to which the above-identified application claims priority under 35 U.S.C. §120.
- ☒ Publications listed on the attached Form PTO-1449 were cited in a foreign search or examination report corresponding to PCT application serial no. PCT/US01/19369 and mailed on April 14, 2003.
- ☐ Enclosed is a copy of a non-English publication(s) \_\_\_\_\_. Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

- ☐ Enclosed is a copy of a non-English publication(s) \_\_\_. English language publication \_\_\_ (copy enclosed) claims priority from this non-English publication.
- ☐ Enclosed is an explanation of non-English publication(s) \_\_\_ for which an English translation is not available.
- ☐ Enclosed is an English translation of non-English publication(s) \_\_\_ cited in the attached Form PTO-1449.
- ☐ Enclosed is a copy of pending patent Application Serial No. \_\_\_.

This Information Disclosure Statement is filed within any one of the following time periods:

- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
- ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in this international application;
- ☒ before the mailing date of a first office action on the merits; or
- ☐ before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO-1449 to the undersigned.

Please direct all written communications in this application to:

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Dated: 12/13/04

Respectfully submitted,

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Please type a plus sign (+) inside this box → ☐

PTO/SB/08A (08-00)

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>			
		Application Number	10/643,853		
		Filing Date	August 19, 2003		
		First Named Inventor	Chien et al.		
		Group Art Unit	1632		
		Examiner Name	Not Assigned		
Sheet	2	of	2	Attorney Docket Number	PP16073.021 (2300-16073.10)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	CA	CHIEN et al., "Use of a Novel Hepatitis C Virus (HCV) Major-Epitope Chimeric Polypeptide for Diagnosis of HCV Infection," Journal of Clinical Microbiology, Washington, DC, US, 37(5):1393-1397 (1999)	
	CB	KASHIWAKUMA et al., "Detection of Hepatitis C Virus Specific Core Protein in Serum of Patients by a Sensitive Fluorescence Enzyme Immunoassay (FEIA)," Journal of Immunological Methods, Elsevier Science Publishers B.V., Amsterdam, NL, 190(1):79-89 (1996)	
	CC	NING YANG et al., "Examination of IGM Antibody to Hepatitis C and Analysis on Hepatitis C Patients' Sera," Zhonghua Weishengwuxue He Mianyixue Zazhi, 15(4):254-257 (1995) XP001121826	
	CD	QI ZIBAI et al., "Evaluation of the Capabilities for Detecting Anti-HCV Core and NS3 Antibodies with Two Anti-HGV EIA Kits of the Third Generation," Zhonghua Weishengwuxue He Mianyixue Zazhi, 19(5):433-435 (1999) XP001121825	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number.

<sup>1</sup> Applicant is to place a check mark here if English language Translation attached.